

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



Applicants: Robert E. Richard et al.  
 Application No.: 10/632,054  
 Date Filed: 07/31/2003  
 Title: IMPLANTABLE OR INSERTABLE MEDICAL DEVICES CONTAINING RADIATION-TREATED POLYMER FOR IMPROVED DELIVERY OF THERAPEUTIC AGENT  
 Group Art Unit: 3736  
 Atty. Docket No.: 02-465

## INFORMATION DISCLOSURE STATEMENT (IDS)

Mail Stop DD  
 Commissioner for Patents  
 P.O. Box 1450  
 Alexandria, VA 22313-1450

SIR:

In accordance with 37 C.F.R. §1.56 and in compliance with 37 C.F.R. §§1.97 and 1.98, the references listed on attached Form PTO/SB/08 and/or subsequently identified herein, are being submitted herewith for consideration by the United States Patent and Trademark Office.

## I. COPIES

- a.  A legible copy of (i) each U.S. and foreign patents; (ii) each publication or that portion which caused it to be listed; and (iii) all other information or that portion which caused it to be listed, is included herewith.
- b.  Any patents, publications or other information which are listed on PTO/SB/08 which are not enclosed herewith were previously cited by or submitted to the PTO in one of the following applications which has been relied upon for an earlier filing date under 35 U.S.C. §120:

U.S. Serial NumberU.S. Filing Date

## II. CONCISE EXPLANATION OF THE RELEVANCE (check at least one box)

- a.  Except as may be indicated below in (b) of this section, all of the patents, publications or other information are in the English language (concise explanation not required).
- b.  A concise explanation of the relevance of all patents, publications or other information listed that is not in the English language is as follows:
- c.  The following additional information is provided for the Examiner's consideration:

III.  CROSS REFERENCE TO RELATED APPLICATION(S)

The Examiner is advised that the following co-pending application(s) contain(s) subject matter that may be related to the present application. By bringing this (these) applications to the Examiner's attention, Applicant(s) does(do) not waive the confidentiality provisions of 35 U.S.C. §122.

Serial No.Filing DateArt Unit

FEES

- IV.  THIS IDS IS BEING FILED UNDER 37 C.F.R. §1.97(b): (check one box)
- a.  within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d) (37 C.F.R. §1.97(b)(1)). No fee or statement is required.
- b.  within three months of the date of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R. §1.97(b)(2)). No fee or statement is required.
- c.  before the mailing date of a first Office Action on the merits (37 C.F.R. §1.97(b)(3)). No fee or statement is required.
- d.  before the mailing date of a first Office Action after the filing of a request for continued examination under § 1.114 (37 C.F.R. § 1.97(b)(4)). No fee or statement is required.
- V.  THIS IDS IS BEING FILED UNDER 37 C.F.R. §1.97(c): (check one box)  
before the mailing date of any of a Final Office Action under 37 C.F.R. §1.113, a Notice of Allowance under 37 C.F.R. §1.311, or an action that otherwise closes prosecution in the application (See 37 C.F.R. §1.97(c)).
- a.  No statement; therefore, charge deposit account 50-1047 the fee set forth in 37 C.F.R. §1.17(p).
- b.  See the statement below. No fee is required.
- VI.  THIS IDS IS BEING FILED UNDER 37 C.F.R. §1.97(d):  
on or before payment of the issue fee and is accompanied by the following:
- 1) a statement under 37 C.F.R. §1.97(e) as provided below; and  
2) charge deposit account 50-1047 the petition fee set forth in §1.17(p).
- VII.  STATEMENT UNDER 37 C.F.R. §1.97(e) (check only one box, if applicable)  
The undersigned hereby states that
- a.  each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of IDS; or
- b.  no item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application, and to knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the IDS was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of this statement, or
- c.  some of the items of information contained in the IDS were cited in a communication from a foreign Patent Office. As to this information, the undersigned states that each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby states that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application or, to the knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the IDS was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of this statement.
- VIII. PAYMENT OF FEES
- A check in the amount of \_\_\_\_\_ is enclosed for the above-identified fee(s).
- Please charge Deposit Account No. 50-1047 in the amount of \$180.00 for the above-indicated fee(s).
- If Applicant has overlooked any additional fees, or if any overpayment has been made, the Commissioner is hereby authorized to credit or debit Deposit Account 50-1047.
- Two Copies of this paper are attached for Deposit Account charges and debits.

It is Applicant(s)' opinion that the claims presently on file patently distinguish the present invention from each of these references. The above references are being cited only in the interests of candor and without any admission that they constitute statutory prior art or contain matter which anticipates the invention or which would render the same obvious, either singly or in a combination, to a person of ordinary skill in the art.

If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule (with a petition if necessary) and charge the appropriate fee to Deposit Account No. 50-1047.

Respectfully submitted,

MAYER FORTKORT & WILLIAMS  
Customer Number 27774

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Attorney for Applicant(s)  
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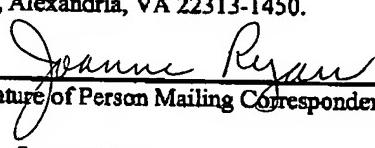
Enclosures:  PTO/SB/08  
 References  
 Foreign Search Report  
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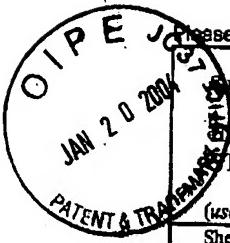
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Joanne Ryan  
Typed or Printed Name of Person Mailing Certificate



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Substitute for form 1449A/PTO  
**INFORMATION DISCLOSURE  
 STATEMENT BY APPLICANT**  
 (use as many sheets as necessary)

Sheet

1

of

3

				<i>Complete if Known</i>
				Application Number
				10/632,054
				Filing Date
				07/31/2003
				First Named Inventor
				Robert E. Richard
				Group Art Unit
				3736
				Examiner Name
				Unassigned
				Attorney Docket Number
				02-465

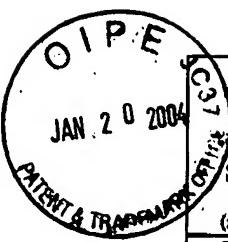
Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Class/Subclass		
1.	2002/0099438 A1	623/1.16	Furst	07/25/2002	
2.	6,335,029 B1	424/423	Kamath et al.	01/01/2002	
3.	6,280,411 B1	103.05/1	Lennox	08/28/2001	
4.	5,258,020	623/1	Froix	11/02/1993	
5.	6,099,562	623/1.46	Ding et al.	08/08/2000	
6.	5,954,706	604/509	Sahatjian	09/21/1999	
7.	5,879,697	424/422	Ding et al.	03/09/1999	
8.	5,716,981	514/449	Hunter et al.	02/10/1998	
9.	5,616,608	514/449	Kinsella et al.	04/01/1997	
10.	5,733,925	514/449	Kunz et al.	03/31/1998	
11.	5,789,018	427/2.3	Engelson et al.	08/04/1998	
12.	5,674,242	606/198	Phan et al.	10/07/1997	
13.	5,304,121	604/53	Sahatjian	04/19/1994	
14.	5,163,952	623/1	Froix	11/17/1992	
15.	4,946,899	525/244	Kennedy et al.	08/07/1990	
16.	5,741,331	623/11	Pinchuk	04/21/1998	
17.	2002/0197296 A1	424/423	Gen	12/26/2002	

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	T
		Office <sup>2</sup>	Number <sup>3</sup>	Class/Subclass			
1.							
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<sup>1</sup> Unique citation designation number. <sup>2</sup> See Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 18 if possible. <sup>6</sup> Applicant is to place a check mark here if English Language Translation is attached.



C-37 Substitute for form 1449A/PTO				<i>Complete if Known</i>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(use as many sheets as necessary)</i>				Application Number	10/632,054
				Filing Date	07/31/2003
				First Named Inventor	Robert E. Richard
				Group Art Unit	3736
				Examiner Name	Unassigned
				Attorney Docket Number	02-465
Sheet	2	of	3		

Examiner Signature		Date Considered	
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<sup>1</sup> Unique citation designation number. <sup>2</sup> See Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 18 if possible. <sup>6</sup> Applicant is to place a check mark here if English Language Translation is attached.



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Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>		<i>Complete if Known</i>	
		Application Number	10/632,054
		Filing Date	07/31/2003
		First Named Inventor	Robert E. Richard
		Group Art Unit	3736
		Examiner Name	Unassigned
Sheet	3	of	3
		Attorney Docket Number	02-465

<b>OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS</b>		
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	1	Reference: Polymer Properties. Thermal Transitions of Homopolymers: Glass Transition & Melting Point. <a href="http://www.sigmaaldrich.com/img/assets/3900/Thermal_Transitions_of_Homopolymers.pdf">http://www.sigmaaldrich.com/img/assets/3900/Thermal_Transitions_of_Homopolymers.pdf</a> .
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	4.	Radiation Processing of Polymer. Radiation Processing in Your Life. <a href="http://www.geocities.com/msen20/Radprocessingofpolymers.pdf">http://www.geocities.com/msen20/Radprocessingofpolymers.pdf</a> .
	5.	Karl J. Hemmerich. Polymer Materials Selection for Radiation-Sterilized Products. <a href="http://www.devicelink.com/mddi/archive/00/02/006.html">http://www.devicelink.com/mddi/archive/00/02/006.html</a> .

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